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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,119	04/13/2007	Timothy Charles Ramsey Prickett	36697.17	1813

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	**PAPER NUMBER**
1641	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,119	PRICKETT ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009 and 29 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-20,23-33,35,36,44,46-48,50 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15,17-19,23-27,33,35,36,44,46-48,50 and 51* is/are rejected.

7)☒ Claim(s) *1-7,9-13,16,20 and 28-32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 20 July 2009 is acknowledged and has been entered. Claims 8, 21, 22, 34, 37-43, 45, and 49 have been cancelled. Claims 1-7, 9-20, 23-33, 35, 36, 44, 46-48, 50, and 51 remain in the case.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 14, 15, 17-19, 23-27, 33, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, particularly the invention commensurate in scope with these claims.

Applicant's specification, while describing and being enabling for determination of skeletal development in pre-adults, and in those suspected of having a skeletal disease or disorder or abnormality, with determinations of the N-terminal fragment of pro-C-type natriuretic peptide (NT-proCNP) in plasma, does not reasonably provide description or

enablement for determinations indicative of skeletal growth potential or skeletal age of a subject. Prickett et al. (Ped. Res. 58: 334, 2005) teach that even in 2005, several years after the instant filing date, further unpredictable studies were required to determine if there were any linkages between levels of NT-proCNP and growth velocity (see e.g.: page 338, col. 1; page 339) and final adult height (i.e. growth potential; see e.g. page 338, col. 2). Applicant's specification provides a mere suggestion to one in the art for further experimentation to determine if the levels of the peptide correlate with skeletal growth potential or skeletal age of a subject. Such experimentation may be "obvious to try", but such an invitation to experiment does not provide an indication that applicant had possession of the invention as claimed at the time the application was filed and does not provide an enabling disclosure. Moreover, it is undisclosed and entirely unclear how one could be assured of the ability to predict skeletal growth potential by comparison of a level of the peptide to a level in a control population that has attained maximum skeletal growth as claimed, other than in the determination of cessation of growth (see e.g. page 28). It is also undescribed and unclear how one could predictably detect skeletal age by comparison to age and sex-matched controls of known skeletal ages because how one determines the skeletal age parameter is not clear and it would seem that a range of control values would be needed for such a comparison if any relationship between peptide level and age could be established in the first place. Thus, applicant was not in possession of the claimed invention at the time of filing and one would not be assured of the ability to perform the methods as instantly disclosed and claimed with any assurance or predictability of success absent further unpredictable experimentation to confirm relationships merely suggested in applicant's specification. Such unpredictable experimentation is undue experimentation.

Applicant's arguments filed 20 July 2009 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

Claims 44, 46-48, 50, and 51 are rejected under 35 U.S.C. 112, first paragraph, for reasons similar to those of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, particularly the invention commensurate in scope with these claims.

As set forth previously, applicant's specification, while describing and being enabling for determination of skeletal development as regards to those patients suspected of having a skeletal disease or disorder or abnormality, is not broadly enabling for diagnostic determinations in a subject generally. As taught in Prickett et al. (Biochem. Biophys. Res. Comm. 286: 513, 2001) and/or the instant specification (e.g. page 14) the level of the peptide fragment is elevated in subjects with heart failure or renal failure. Thus, the detection of an elevated level in such a patient population, even in those patients suspected of having a skeletal disease or disorder or abnormality, would not be indicative of skeletal disease or disorder. Thus, absent further written description and guidance from applicant, the specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant's arguments filed 20 July 2009 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, the interrelationships of the steps of the method are not clear because it is not clear how diagnosis of diseases or disorders relate to predictions of skeletal growth potential.

Applicant's arguments filed 20 July 2009 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

Claims 1, 14-16, 29, 33, 36, 44, and 48, and claims dependent thereupon, are objected to because of the following informalities: the acronym "NT-CNP" should not be used until fully

defined at its first occurrence in the independent claim, such as by --N-terminal pro-C-type natriuretic peptide (NT-CNP)--. Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33 and 36 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Prickett et al. (Biochem. Biophys. Res. Comm. 286: 513, 2001) for reasons of record.

Applicant's arguments filed 20 July 2009 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above. With regard to the kit (claim 33) and the binding agent (claim 36) claims, the examiner would again note that: a recitation of intended use is accorded patentable weight only to the extent that it limits the actual components of a composition; and, in the instant case the intended use does not affect the components in any way which distinguishes over the subject matter taught or suggested by the reference. Moreover, the printed matter in no way depends on the kit, and the kit components in no way depend on the printed matter. All the printed matter does is to teach an alternative use for an existing product. As pointed out in In re Gulack 703 F2d 1381 (Fed Cir. 1983), "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 33, 35, and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Prickett et al. (Biochem. Biophys. Res. Comm. 286: 513, 2001) in view of Buechler (US 2003/0219734) for reasons of record in the prior rejection of these claims.

Applicant's arguments filed 20 July 2009 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above. With regard to the kit (claims 33 and 35) and the binding agent (claim 36) claims, the examiner would again note that: a recitation of intended use is accorded patentable weight only to the extent that it limits the actual components of a composition; and, in the instant case the intended use does not affect the components in any way which distinguishes over the subject matter taught or suggested by the reference. Moreover, the printed matter in no way depends on the kit, and the kit components in no way depend on the printed matter. All the printed matter does is to teach an alternative use

for an existing product. As pointed out in In re Gulack 703 F2d 1381 (Fed Cir. 1983), "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability."

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
November 25, 2009

/Shafiqul Haq/
Primary Examiner, Art Unit 1641